

Douglas S. Eakeley (DE-7060)  
John R. Middleton, Jr. (JM-7724)  
**LOWENSTEIN SANDLER PC**  
Attorneys At Law  
65 Livingston Avenue  
Roseland, New Jersey 07068  
973.597.2500  
Attorneys for Plaintiff

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ORTHO-McNEIL PHARMACEUTICAL, INC.,

Plaintiff,

v.

KALI LABORATORIES, INC.,  
PAR PHARMACEUTICAL COMPANIES, INC.,  
PAR PHARMACEUTICAL, INC.,  
BARR LABORATORIES, INC.,  
and CARACO PHARMACEUTICAL  
LABORATORIES, LTD.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT  
(Jury Demand)**

In this patent infringement action, Plaintiff Ortho-McNeil Pharmaceutical, Inc., for its complaint against Defendants Kali Laboratories, Inc., Par Pharmaceutical Companies, Inc., Par Pharmaceutical, Inc., Barr Laboratories, Inc., and Caraco Pharmaceutical Laboratories, Ltd., alleges as follows:

## **PARTIES**

### **A. Ortho-McNeil**

1. Plaintiff Ortho-McNeil Pharmaceutical, Inc. (“Ortho-McNeil”) is a corporation incorporated under the laws of the State of Delaware with its principal place of business at 1000 U.S. Route 202, Raritan, New Jersey 08869.

### **B. Kali/Par**

2. Upon information and belief, Defendant Kali Laboratories, Inc. (“Kali”) is a corporation incorporated under the laws of New Jersey. Upon information and belief, Kali maintains its principal place of business at 71 Suttons Lane, Piscataway, New Jersey 08854.

3. Upon information and belief, Defendant Par Pharmaceutical Companies, Inc. (“Par Co.”) is a corporation incorporated under the laws of Delaware. Upon information and belief, Par Co. maintains an office constituting its principal executive offices and/or its principal place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

4. Upon information and belief, Defendant Par Pharmaceutical, Inc. (“Par”) is a corporation incorporated under the laws of Delaware. Upon information and belief, Par maintains an office constituting its principal executive offices and/or its principal place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

### **C. Barr**

5. Upon information and belief, Defendant Barr Laboratories, Inc. (“Barr”) is a Delaware corporation having its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

### **D. Caraco**

6. Upon information and belief, Defendant Caraco Pharmaceutical Laboratories, Ltd. (“Caraco”) is a Michigan corporation having its principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan, 48202.

### **JURISDICTION AND VENUE**

7. This action for patent infringement arises under 35 U.S.C. § 100 *et seq.*

8. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338.

#### **A. Kali/Par**

9. Venue is proper in this Court under Title 28, United States Code §§ 1391(c) and 1400(b) against Defendants Kali, Par Co., and Par because, among other reasons, Defendant Par Co. and its wholly owned subsidiaries Defendants Par and Kali reside in and are subject to personal jurisdiction in this judicial district.

#### **B. Teva/Barr**

10. Venue is proper in this Court under Title 28, United States Code §§ 1391(c) and 1400(b) against Defendant Barr because, among other reasons, Defendant Barr resides in and is subject to personal jurisdiction in this judicial district.

#### **C. Caraco**

11. Venue is proper in this Court under Title 28, United States Code §§ 1391(b) & (c) and 1400(b) against Defendant Caraco because, among other reasons, as alleged *infra* ¶ 23, Caraco's acts of infringement have occurred in this judicial district and, upon information and belief, Caraco has an established distribution network in place for delivery of the infringing products into this judicial district, subjecting Caraco to personal jurisdiction in this judicial district.

### **GENERAL ALLEGATIONS**

12. On August 9, 1994, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 5,336,691 ("the '691 Patent").

13. Ortho-McNeil is the current assignee of the '691 Patent.

14. Ortho-McNeil owns all rights, title and interest in the '691 Patent.

15. Ortho-McNeil markets the drug covered by New Drug Application (“NDA”) No. 21-123 under the tradename Ultracet®, the active ingredients of which are tramadol hydrochloride and acetaminophen (hereinafter, “Ultracet®” or “the Ultracet® drug product”).

16. On or about January 20, 2004, Ortho-McNeil filed an application to reissue the ‘691 Patent with the USPTO to correct certain errors in claims 1 to 5 and 7 to 15 of the ‘691 Patent. The application for reissue has been examined by the USPTO, and the USPTO reissued the ‘691 Patent as Reissue Patent No. RE39221 (“the RE221 Patent”) on August 1, 2006. The RE221 Patent includes claims 2-23, which were not contained in the ‘691 Patent.

17. Ortho-McNeil is the current assignee of the RE221 Patent.

18. Ortho-McNeil owns all rights, title and interest in the RE221 Patent.

19. Upon information and belief, on or about April 22, 2005, Defendants Par Co., Par and/or Kali began marketing a generic version of Ultracet® in, among other places, the District of New Jersey. Upon information and belief, Defendants Kali, Par Co. and/or Par continue to make, use, offer to sell, sell, and/or import their generic version of Ultracet®. Upon information and belief, Defendants Kali, Par Co., and Par’s manufacture, use, offer to sell, sale and/or importation of their generic version of Ultracet® infringes one or more of claims 2-63 of the RE221 Patent.

20. Upon information and belief, Defendants Kali, Par Co. and Par have infringed one or more of claims 2-63 of the RE221 Patent willfully, making this an exceptional case and justifying the award of attorneys’ fees pursuant to 35 U.S.C. § 285 (and/or § 271), as well as increased damages (up to treble) pursuant to 35 U.S.C. § 284 (and/or § 271).

21. Upon information and belief, on or about July 26, 2005, Defendant Barr began marketing, selling, importing and/or offering to sell a generic version of Ultracet® pursuant to an ANDA it purchased from Teva Pharmaceuticals USA, Inc. and/or Teva

Pharmaceuticals Industries, Ltd. in, among other places, the District of New Jersey. Upon information and belief, Defendant Barr continues to make, use, offer to sell, and/or import its generic version of Ultracet®. Upon information and belief, Defendant Barr's manufacture, use, offer to sell, and/or importation of its generic version of Ultracet® infringes one or more of claims 2-63 of the RE221 Patent.

22. Upon information and belief, Defendant Barr has infringed one or more of claims 2-63 of the RE221 Patent willfully, making this an exceptional case and justifying the award of attorneys' fees pursuant to 35 U.S.C. § 285 (and/or § 271), as well as increased damages (up to treble) pursuant to 35 U.S.C. § 284 (and/or § 271).

23. Upon information and belief, in or about December 2005, Defendant Caraco began marketing a generic version of Ultracet® in, among other places, the District of New Jersey. Upon information and belief, Defendant Caraco continues to make, use, offer to sell, sell, and/or import its generic version of Ultracet®. Upon information and belief, Defendant Caraco's manufacture, use, offer to sell, sale and/or importation of its generic version of Ultracet® infringes one or more of claims 2-63 of the RE221 Patent.

24. Upon information and belief, Defendant Caraco has infringed one or more of claims 2-63 of the RE221 Patent willfully, making this an exceptional case and justifying the award of attorneys' fees pursuant to 35 U.S.C. § 285 (and/or § 271), as well as increased damages (up to treble) pursuant to 35 U.S.C. § 284 (and/or § 271).

### **COUNT ONE**

#### **(Infringement of the RE221 Patent against Defendants Kali, Par Co. and Par)**

25. Ortho-McNeil incorporates and realleges paragraphs 1 through 24 above, as if set forth in full herein.

26. Through the conduct alleged above, Kali, Par Co. and/or Par have infringed, and continue to infringe, one or more of claims 2-63 of the RE221 Patent.

27. Upon information and belief, Kali, Par Co. and/or Par's infringement of claims 2-63 of the RE221 Patent has been willful.

28. By reason of Kali, Par Co. and/or Par's infringement of claims 2-63 of the RE221 Patent, Kali, Par Co. and/or Par have caused and continue to cause Ortho-McNeil to suffer damage and irreparable harm. Upon information and belief, Kali, Par Co. and/or Par's infringement of claims 2-63 of the RE221 Patent will continue unless enjoined by this Court.

29. Ortho-McNeil has no adequate remedy at law for Kali, Par Co. and/or Par's infringement of claims 2-63 of the RE221 Patent.

30. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Ortho-McNeil's reasonable attorneys' fees.

## **COUNT TWO**

### **(Infringement of the RE221 Patent against Defendant Barr)**

31. Ortho-McNeil incorporates and realleges paragraphs 1 through 24 above, as if set forth in full herein.

32. Through the conduct alleged above, Barr has infringed, and continues to infringe, one or more of claims 2-63 of the RE221 Patent.

33. Upon information and belief, Barr's infringement of claims 2-63 of the RE221 Patent has been willful.

34. By reason of Barr's infringement of claims 2-63 of the RE221 Patent, Barr has caused and continues to cause Ortho-McNeil to suffer damage and irreparable harm. Upon information and belief, Barr's infringement of claims 2-63 of the RE221 Patent will continue unless enjoined by this Court.

35. Ortho-McNeil has no adequate remedy at law for Barr's infringement of claims 2-63 of the RE221 Patent.

36. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Ortho-McNeil's reasonable attorneys' fees.

### **COUNT THREE**

#### **(Infringement of the RE221 Patent against Defendant Caraco)**

37. Ortho-McNeil incorporates and realleges paragraphs 1 through 24 above, as if set forth in full herein.

38. Through the conduct alleged above, Caraco has infringed, and continues to infringe, one or more of claims 2-63 of the RE221 Patent.

39. Upon information and belief, Caraco's infringement of claims 2-63 of the RE221 Patent has been willful.

40. By reason of Caraco's infringement of claims 2-63 of the RE221 Patent, Caraco has caused and continues to cause Ortho-McNeil to suffer damage and irreparable harm. Upon information and belief, Caraco's infringement of claims 2-63 of the RE221 Patent will continue unless enjoined by this Court.

41. Ortho-McNeil has no adequate remedy at law for Caraco's infringement of claims 2-63 of the RE221 Patent.

42. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Ortho-McNeil's reasonable attorneys' fees.

### **RELIEF SOUGHT**

**WHEREFORE**, Plaintiff Ortho-McNeil requests that:

A. Judgment be entered that Kali, Par Co., Par, Barr, and Caraco have infringed, either literally or under the doctrine of equivalents, one or more of claims 2-63 of the RE221 Patent;

B. Judgment be entered that the manufacture, use, sale or offer to sell within the United States, or importation into the United States, by Kali, Par Co. and/or Par of their generic copy of Ultracet® infringes one or more of claims 2-63 of the RE221 Patent;

C. Judgment be entered that the manufacture, use, sale or offer to sell within the United States, or importation into the United States, by Barr of its generic copy of Ultracet® infringes one or more of claims 2-63 of the RE221 Patent;

D. Judgment be entered that the manufacture, use, sale or offer to sell within the United States, or importation into the United States, by Caraco of its generic copy of Ultracet® infringes one or more of claims 2-63 of the RE221 Patent;

E. Judgment be entered that Kali, Par Co., Par, Barr, and Caraco's infringement of claims 2-63 of the RE221 Patent has been willful;

F. A permanent injunction be granted preventing Kali, Par Co., Par, Barr, and Caraco, their officers, directors, agents, servants, employees, successors and assigns, and all others in concert and privity with them from infringing claims 2-63 of the RE221 Patent;

G. Ortho-McNeil be awarded its damages for Kali, Par Co. and/or Par's manufacturing, use, sales, offers to sell and/or importations of their generic version of Ultracet®;

H. Ortho-McNeil be awarded its damages for Barr's manufacturing, use, sales, offers to sell and/or importations of its generic version of Ultracet®;

I. Ortho-McNeil be awarded its damages for Caraco's manufacturing, use, sales, offers to sell and/or importations of its generic version of Ultracet®;

J. Judgment be entered that, in view of Kali, Par Co. and/or Par's relevant acts, including Kali, Par Co. and/or Par's willful infringement, this case is an exceptional case under 35 U.S.C. § 285, entitling Ortho-McNeil to an award of its reasonable attorneys' fees;



K. Judgment be entered that, in view of Barr's relevant acts, including Barr's willful infringement, this case is an exceptional case under 35 U.S.C. § 285, entitling Ortho-McNeil to an award of its reasonable attorneys' fees;

L. Judgment be entered that, in view of Caraco's relevant acts, including Caraco's willful infringement, this case is an exceptional case under 35 U.S.C. § 285, entitling Ortho-McNeil to an award of its reasonable attorneys' fees;

M. Ortho-McNeil be awarded its reasonable attorneys' fees;

N. Ortho-McNeil be awarded pre-judgment and post-judgment interest on each and every award;

O. Ortho-McNeil be awarded its costs and expenses; and

P. Ortho-McNeil be granted such other and further relief as the Court may deem just and proper.

### **JURY DEMAND**

Plaintiff Ortho-McNeil hereby demands a trial by jury of all issues so triable pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Respectfully Submitted,

**Of Counsel:**

David T. Pritikin  
Lisa A. Schneider  
Sidley Austin LLP  
Bank One Plaza  
10 S. Dearborn Street  
55th Floor  
Chicago, Illinois 60603  
312.853.7000

- and -

Jeffrey P. Kushan  
David W. Woodward  
David A. Steffes  
Sidley Austin LLP  
1501 K Street, N.W.  
Washington, D.C. 20005  
202.736.8000

- and -

Michael D. Hatcher  
Sidley Austin LLP  
717 North Harwood, Suite 3400  
Dallas, Texas 75201  
214.981.3300

Dated: August 1, 2006

s/ Matthew J. Atlas

Douglas S. Eakeley (DE-7060)  
John R. Middleton, Jr. (JM-7724)  
Matthew J. Atlas (MA-4210)  
Lowenstein Sandler PC  
65 Livingston Avenue  
Roseland, NJ 07068  
TEL: (973) 597-2500

Attorneys for Plaintiff  
Ortho-McNeil Pharmaceutical, Inc.

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

I hereby certify that the matter in controversy in this case is also the subject of lawsuits currently pending in this Court, Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc., Civil Action No. 02-5707 (JCL) and Ortho-McNeil Pharmaceutical, Inc. v. Teva Pharmaceutical Indus., Ltd. et al., Civil No. 04-886 (D.N.J.), and before the U.S. Court of Appeals for the Federal Circuit, Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories, Ltd., Appeal No. 06-1102 (on appeal from Civil Action No. 04-CV-73698 (E.D. Mich.)), in that the patent that reissued as the patent in suit in this case is in suit in the aforementioned cases.

By: s/ Matthew J. Atlas  
Matthew J. Atlas (MA-4210)

Dated: August 1, 2006